

REMARKS

This Amendment is filed in response to the Office Action dated April 27 2007. By this Amendment, claims 1, 29 and 32 have been amended to better define the presently claimed invention. Claims 2, 5, 28, 30, 39 and 40 were amended to maintain consistency in claim language in view of the amendments to claims 1 and 32. Claims 1-5 and 24-40 remain pending in this application. Applicants have carefully reviewed the arguments presented in the Office Action and respectfully request reconsideration of the claims in view of the remarks presented below.

In the outstanding April 27, 2007 Office Action, claim 29 was rejected under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement. In so rejecting the claim, the Examiner stated that the "limitation of claim 29 that the radiopaque marker further comprises a coating is not supported by the original specification." Applicants have amended claim 29 to make it clear that the marker body itself takes the form of a coating, not that the marker is covered with an additional coating, as interpreted by the Examiner. It is respectfully submitted that the specification does indeed support the subject matter recited in claim 29 in paragraph [00042]. In particular, the specification states that "One method of manufacturing the above-described guidewires is through extrusion coating. Specifically, the radiopaque polymer is extrusion coated over a PTFE mandrel." Accordingly, it is believed that the specification clearly states that the radiopaque marker itself can comprise a coating. Therefore, it is believed that claim 29 satisfies the requirements of § 112, first paragraph.

Claims 1-4, 24-26, 28, 30, 32-37, 39 and 40 were rejected under § 102(e) as being anticipated by the U.S. Publication No. 2003/0164063 to Elliott (the "Elliott reference").

In so rejecting the claims, the Examiner states, in paragraph 6 of the April 27, 2007

Office Action:

.....the preamble 'radiopaque marker' is given little patentable weight for two reasons. First, it appears the preamble is reciting purpose or intended use of the claimed article, which would only be given weight with regard to any structural differences the intended use results in. Second, if the preamble is not merely reciting purpose or intended use the only structural limitation provided by 'radiopaque marker' is an article that is opaque to radiation, such as x-rays. This limitation would cover any article as long as it is opaque to radiation. The limitation that the marker is "for a medical device" is given little patentable weight because it is merely an intended use of the marker. Furthermore, the limitation that the marker "have a length, thickness, and cross-sectional size selected for attachment to the medical device...flexibility of the medical device" is given little patentable weight. Medical devices come in a myriad of different sizes including very small and very large objects. Therefore, to have length, thickness, and cross-sectional size selected for attachment does not limit the marker to any particular size. Thus, the radiation shield taught by Elliott would have a size that would fall within the claimed invention. The article of Elliott is a radiation-shielding article (p. 3, paragraph 56) and therefore anticipates the structural limitations provided by the preamble."

The Examiner states that the only structural limitation provided by 'radiopaque marker' is an article that is opaque to radiation, such as x-rays. Applicants strongly disagree with the Examiner's position. Significantly, independent claims 1 and 32 recite a radiopaque marker for a medical device comprising a marker body having a length, thickness and cross-sectional size selected for attachment to the medical device to thereby provide desired radiopacity without substantially affecting flexibility of the medical device. These structural recitations are more than just mere functional language. Therefore, the

Examiner is incorrect in stating that the only structural limitation provided by 'radiopaque marker' is an article that is opaque to radiation.

Even the Examiner acknowledges that these limitations are structural but provides these structural recitations little patentable weight. In the Office Action, the Examiner states: " Furthermore, the limitation that the marker 'have a length, thickness, and cross-sectional size selected for attachment to the medical device...flexibility of the medical device' is given little patentable weight." Again, Applicants strongly disagree with the Examiner's position. These limitations are certainly significant in determining the patentability of the presently claimed invention and the Examiner is incorrect in not giving them their due weight in the patentability determination. Significantly, the Elliott reference is not concerned with increasing radiopacity, or for that matter, providing a medical device or any device with a marker sized for attachment thereto to increase the radiopacity of the device. The Elliott reference merely teaches a metal/polymer composite material that can be used as a replacement for lead. (see paragraph [0002] of the Elliott reference). The Elliott reference provides absolutely no disclosure that such a composite material could be used to increase the radiopacity of another device, no less a medical device. Even more significant, the Elliott reference fails to teach a marker body having a length, thickness and cross-sectional size selected for providing radiopacity **without effecting the flexibility of a medical device to which it is attached.** Therefore, Applicants submit that the Examiner's disregard for the structural recitations found in the pending claims leads him to improperly reject these claims over the Elliott reference. Accordingly, Applicants submit that each of independent claims 1 and 32

recite a structure that is not even remotely taught or contemplated by the cited Elliott reference. For at this reason alone, it is respectfully submitted that independent claims 1 and 32 as well as their respective dependent claims recite patentable subject matter.

Moreover, it is respectfully submitted that since the body of independent claims 1 and 32 recite the phrase "medical device" and specifically a marker body having a length, thickness and cross-sectional size selected for attachment to the medical device and without substantially affecting the flexibility of the medical device, each of the pending claims do indeed recite structural limitations beyond a mere intended use. Accordingly, as addressed above, it is respectfully submitted that since the Elliott reference is not even concerned with providing a marker for a medical device, or for that matter, providing any type of marker which, *inter alia*, provides radiopacity without substantially affecting the flexibility of the medical device, then the Elliott reference does not anticipate the subject matter recited in independent claims 1 and 32 as well as their respective dependent claims.

Applicants further submit that the subject matter of at least claims 28, 29, 30 and 40 is not anticipated by the Elliott reference. In rejecting these claims, the recitation that the marker forms a coating or an extrusion coating was dismissed by the Examiner as providing functional language for which no patentable weight would be given. However, Applicants strongly disagree with the Examiner's position since the marker in these claims is expressed in terms that defines its structural nature as being a coating, as opposed to being a preformed solid object that is simply attached to a device. Since the Elliott reference fails to even disclose the use of the composite material to create a

marker, it is further incorrect to take the position that it would have been obvious to use the Elliott material in the form of a coating or extrusion coating to provide a marker for a device. Accordingly, it is submitted that claims 28, 29, 30 and 40 are allowable over the Elliott reference for at least this reason as well.

Therefore, it is respectfully submitted that Elliott does not anticipate claims 1-4, 24-26, 28, 30, 32-37, 39 and 40 because it does not teach each and every limitation recited in the claims. Accordingly, it is submitted that the rejection of claims 1-4, 24-26, 28, 30, 32-37, 39 and 40 under § 102(e) in view of the Elliott reference is incorrect and should be withdrawn.

Claims 5, 27, 31 and 38 were rejected under § 103(a) as being unpatentable over Elliott. In rejecting claim 5, the Examiner states the following in the Office action:

Elliott teaches all that is claimed in claim 1 as shown above, and teaches that the article is manufactured as a radiation shield. Elliott fails to teach that the article is necessarily formed to define a tubular structure. However, it would have been obvious to one having ordinary skill in the art at the time the Applicant's invention was made that depending on the shape of the object the article of Elliott is providing a radiation shield to would determine the shape of the article of Elliott.

The Examiner then concluded that "it would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to form the radiation shield of Elliott to define a tubular structure when the object shielded from radiation was a tubular shape." It is respectfully submitted, however, that claim 5 is not obvious in view of the teachings of the Elliott reference. Even assuming that one of ordinary skill in the art would take into consideration a shape of an object which the Elliott reference might contemplate as providing a radiation shield, there is no teaching in the Elliott reference of

a medical device which would require a marker body having a tubular form or for that matter, whether a tubular form would indeed provide the radiation shield apparently contemplated by the Elliott reference. Therefore, in addition to claim 5 being allowable over the Elliott reference in view of its dependency from independent claim 1, it is respectfully submitted that claim 5 is also allowable due to the fact that one of ordinary skill in the art would not have contemplated making a radiopaque marker in a tubular shape in view of the teachings of the Elliott reference.

In rejecting claims 27 and 38, the Examiner states the following in the Office action:

Elliott teaches all that is claimed in claims 1 and 32 as shown above, but failed to teach that the article further comprises an antioxidant. However, it is well known in the art that antioxidants are added to elastomers in order to improve prevent oxidative decomposing and therefore, have longer stability in life. Therefore, it would have been obvious to one having ordinary skill in the art to add an antioxidant to an article formed of Pebax in order to increase the stability and life of the article, since antioxidants prevent oxidation and decomposition caused by oxidation.

It is respectfully submitted that claims 27 and 38 also define subject matter which is not obvious in view of the Elliott reference. As stated above, in rejecting claims 27 and 38, the Examiner stated that adding antioxidants to elastomers is well known in the art for preventing oxidative decomposing. However, the Examiner has provided no evidence supporting this conclusion but merely states that the Elliott reference contemplates the same. Accordingly, the Examiner has failed to provide a *prima facia* case of obviousness regarding these claims. Therefore, it is respectfully submitted that in addition to their allowability in view of the dependence from their respective independent claims, it is

respectfully submitted that claims 27 and 38 recite allowable subject matter since the Examiner has not provided a *prima facia* case of obviousness with respect to the claims

Finally, as to claim 31, the Examiner states:

.....although what the medical device is with regard to the marker is given little patentable weight because it is merely further defining an intended use for the claimed marker, this limitation adds at least some type of maximum size requirement to the size limitations in claim 1. Specifically, the marker in claim 31 is required to have a length, thickness, and cross-sectional size selected for attachment to a stent, guide wire, balloon or embolic filter which are all relatively small articles. However, there is still no specific size requirement and Elliott teaches many different sizes of article having different sizes, so it would be obvious to one having ordinary skill in the art at the time Applicant's invention was made the article Elliott would be formed with the length, thickness, and cross-sectional size desired for the intended end result of the desired article produced.

It is also respectfully submitted that claim 31 is non-obvious in view of the teachings of the Elliott reference. Again, the Elliott reference simply does not contemplate providing a medical device with a radiopaque marker and thus does not contemplate a marker sized for attachment to a stent, guide wire, balloon or embolic filter. Thus, in addition to its allowability due to its dependence from independent claim 1, it is respectfully submitted that claim 31 also defines allowable subject matter since one of ordinary skill in the art would not have been inclined to devise a marker sized for attachment to a stent, guide wire, balloon or embolic filter in view of the disclosure of the Elliott reference.

Accordingly, it is respectfully submitted that Elliott does not render obvious the subject matter recited in claims 5, 27, 31 and 38. As such, it is respectfully submitted that the rejections of claims 5, 27, 31 and 38 under § 103(a) were improper.

In view of the foregoing, it is respectfully urged that all of the present claims of the application are patentable and in a condition for allowance. The undersigned attorney

can be reached at (310) 824-5555 to facilitate prosecution of this application, if necessary.

In light of the above amendments and remarks, Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Please charge any additional fee or credit any overpayment to our Deposit Account No. 06-2425. A duplicate copy of this paper is enclosed.

Respectfully submitted,

FULWIDER PATTON LLP

By: THM

Thomas H. Majcher
Registration No. 31,119

THM:lm
Howard Hughes Center
6060 Center Drive, Tenth Floor
Los Angeles, CA 90045
Telephone: (310) 824-5555
Facsimile: (310) 824-9696
Customer No. 24201
193556.1